28. A medical device according to claim 21 wherein the balloon comprises a portion of a balloon catheter.

I. PRELIMINARY REMARKS

The present application is a continuation of parent US 6,027,779 (SN 08/247,960), which is a CIP of US 6,025,044 (SN. 08/204,708), which is a CIP of US 6,159,565 (SN. 08/108,963). The issued patents are referred to hereinafter as the parent patents.

The Commissioner is requested to charge the necessary fees for the 3 month extension of time, RCE, and additional claims to deposit account number 07-1729.

Basis for the amendments and new claims is found throughout the specification, see in particular Figure 1, page 5, lines 1-19 and page 12, line 32 to page 13, line 7.

II. APPLICANTS' INVENTION

The present invention relates to a catheter balloon made of tube having a microstructure of nodes and fibrils such as porous expanded polytetrafluoroethylene (PTFE), further including a non-porous coating over the porous microstructure. The coating renders the balloon non-porous. The thinness, flexibility and strength of the construction allow the resulting balloon to be collapsed to a small first diameter for insertion into a vascular conduit to a desired location at which it can be inflated to the maximum diameter of the tube in the fashion of a conventional polethylene terephthalate (PET) catheter balloon. The balloon of the present invention is superior to such conventional balloons again due to its flexibility, thinness, strength and lubricious materials.

III. REJECTION OF CLAIMS 1-9 UNDER USC 103(a) AS UNPATENTABLE OVER BUCK et al., US 4,925,710 IN VIEW OF GORE, US 3,593,566 AND SOLTESZ, US 5,254,107.

Buck et al. teach the manufacture of wire insulation and tubes which might be used for automotive cables or medical catheters. Gore teaches the manufacture of porous expanded PTFE while Soltesz teaches the construction of a catheter tube having a middle layer of wire reinforcement which is enclosed by inner and outer thermoplastic sections wherein the inner section may be PTFE or the like. The claims are rejected as obvious over the combination of the three cited references. The

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Examiner has concluded that one of ordinary skill would have been motivated to use or easily adapt the teachings of Gore for the purpose of obtaining a non-porous catheter balloon comprising permeable and porous ePTFE (having a microstructure of nodes and fibrils) provided with a non-porous coating, and that the present invention is an obvious modification of the cited art.

Applicants respectfully disagree with the Examiner's conclusion as follows.

First, the claims as amended state within the body of the claim that the medical device is specifically an inflatable balloon. As supported by the specification, this requires that the balloon is adequately thin and flexible to be compacted to a small, collapsed state (e.g., per Figure 14) and inflatable to a larger shape of round cross section.

Secondly, none of the three cited references teach or suggest in any way the construction of a catheter balloon as claimed, a thin and very flexible catheter balloon that is collapsible to a small size for insertion into a body conduit and subsequently inflatable, and readily collapsible again to the small size for removal from the body conduit. Indeed, not one of the cited references makes any suggestion whatsoever of making a catheter balloon of any type.

Next, neither of the tubes taught by Buck et al. and Soltesz are flexible to the extent that anyone would consider them adequately flexible to be compacted to a small size and subsequently inflated to their full size for use as a balloon. The tubes of Buck et al. and Soltesz are of round cross section in their relaxed state (i.e., not subjected to internal pressure such as the air pressure necessary to inflate a balloon). The tube of the present invention is flexible to the extent that it collapses to a non-round cross section absent an internal pressure.

Further, both Buck et al. and Soltesz are made from materials that are impermeable through their thickness (hence the lack of flexibility noted in the above paragraph). Why would one of ordinary skill consider combining them with a porous flexible material when such a combination is already limited by the lack of flexibility of the materials taught by the references? Likewise, why combine them to achieve impermeability when the materials taught by Buck et al. and Soltesz are already impermeable?

With regard to the fillers used in the tube of Buck et al. (which include hollow microspheres that may induce closed-cell porosity but which remains impermeable, as noted by the Examiner), the Examiner further noted that Buck et al. also state that fillers in various other shapes may also be used. However, there remains no suggestion to create any permeable wall by the use of fillers of any type or shape whatsoever; the tube wall clearly remains impermeable. Consequently, it is still the Applicants' position that there is no reason to combine the flexible and porous material of Gore with the inflexibl and non-porous materials of Buck et al. and Soltesz.

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As to Gore, while Gore states that his material can be laminated to other materials, he still only specifically teaches porous materials. There is no suggestion in the entire document, including any of the 16 examples (some of which teach lamination to result in a final porous, permeable material) to create an impermeable material beginning with the porous Gore material as a substrate. Further, even if their were such an inference, there is still no suggestion whatsoever that a flexible, inflatable and collapsible catheter balloon might be made.

The Examiner points to Soltesz regarding his teaching of the construction of a catheter tube as further suggestion that the catheter balloon of the present invention is obvious. However, the reference teaches the construction of a catheter tube that is strong and adequately rigid for good "pushability" (i.e., column strength) as required for insertion into a lengthy vasculature. The rigidity (and lack of flexibility) required for this use as taught by Soltesz is entirely contrary to the flexibility that is a fundamental attribute of the present balloon. Clearly, Soltesz teaches away.

In summary, there is nothing in these references, alone or in combination, that teaches or suggests the construction of a catheter balloon from a porous substrate, particularly one having a microstructure of nodes and fibrils, rendered non-porous by a suitable coating over that substrate.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

The applicants believe that their claims are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully Submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 1-9 have been amended as follows:

1. A medical device [non-porous catheter balloon] comprising permeable, porous expanded polytetrafluoroethylene tube having a microstructure of nodes interconnected by fibrils and provided with a non-porous coating over the porous expanded polytetrafluoroethylene to render the tube[balloon] non-porous, wherein said tube is configured as an inflatable balloon.

2. A medical device [non-porous catheter balloon] according to claim 1 wherein the non-porous coating comprises fluorinated ethylene propylene.

3. A medical device [non-porous catheter balloon] according to claim 1 wherein the non-porous coating comprises an adhesive.

4. A medical device [non-porous catheter balloon] according to claim 3 wherein the adhesive comprises a thermoplastic adhesive.

5. A medical device [non-porous catheter balloon] according to claim 4 wherein the thermoplastic adhesive is a thermoplastic fluoropolymer.

6. A medical device [non-porous catheter balloon] according to claim 1 wherein the porous expanded polytetrafluoroethylene comprises multiple layers[porous expanded polytetrafluoroethylene].

7. A medical device [non-porous catheter balloon] according to claim 1 wherein the balloon is an inelastic balloon.

8. A medical device [non-porous catheter balloon] according to claim 1 wherein the [non-porous coating comprises multiple layers of porous polytetrafluoroethylene] balloon comprises a portion of a balloon catheter.

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9. A medical devic [non-porous catheter balloon] according to claim 1 wherein the non-porous coating is a continuous coating.

Please add the following new claims:

10. A medical device comprising a tube having a node and fibril microstructure, the tube being non-porous and configured as an inflatable balloon

11. A medical device according to claim 10 wherein the tube includes a non-porous coating.

12. A medical device according to claim 11 wherein the non-porous coating comprises fluorinated ethylene propylene.

13. A medical device according to claim 11 wherein the non-porous coating comprises an adhesive.

14. A medical device according to claim 13 wherein the adhesive comprises a thermoplastic adhesive.

15. A medical device according to claim 14 wherein the thermoplastic adhesive is a thermoplastic fluoropolymer.

16. A medical device according to claim 10 wherein the tube comprises porous expanded polytetrafluoroethylene.

17. A medical device according to claim 16 wherein the tube comprises multiple layers of porous expanded polytetrafluoroethylene.

18. A medical device according to claim 10 wherein the balloon is an inelastic balloon.

19. A medical device according to claim 10 wherein the balloon comprises a portion of a balloon catheter.

20. A medical device according to claim 10 wherein the non-porous coating is a continuous coating.

21. A medical device comprising an inflatabl balloon formed from porous expanded polytetrafluoroethylene.

22. A medical device according to claim 21 wherein the balloon includes a non-porous coating comprising fluorinated ethylene propylene.

23. A medical device according to claim 21 wherein the balloon includes a non-porous coating comprising an adhesive.

24. A medical device according to claim 23 wherein the adhesive comprises a thermoplastic adhesive.

25. A medical device according to claim 24 wherein the thermoplastic adhesive is a thermoplastic fluoropolymer.

26. A medical device according to claim 21 wherein the balloon comprises multiple layers of porous expanded polytetrafluoroethylene.

27. A medical device according to claim 21 wherein the balloon is an inelastic balloon.

28. A medical device according to claim 21 wherein the balloon comprises a portion of a balloon catheter.